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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,577	11/18/2003	Karen Giroux	01435.062US1	6252

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VIKSNINS HARRIS & PADYS PLLP
P.O. BOX 111098
ST. PAUL, MN 55111-1098

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,577	GIROUX, KAREN	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-21,30,32,40,41,52,56-58 and 80-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-21,30,32,40,41,52,56-58 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 1/25/2010. Claims 1-17, 22-29, 31, 33-39, 42-51, 53-55 are canceled. Claims 18-21, 30, 32, 40, 52, 56-58 and 80 are amended. Claims 18-21, 30, 32, 40, 41, 52, 56-58 and 80-82 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 18-21, 30, 32, 40, 41, 56-58, 80 and 82 are rejected under 35 U.S.C. 102(a) as being anticipated by Sirhan et al. (WO 2002/056790) for reasons of record and modified to address the amendment.

3. Sirhan discloses medical devices such as vascular stents and grafts (page 1, para. 2) for delivery of active agent that includes anti-inflammatory agent and others such as antiproliferatives, antivirals, antineoplastics and combinations (page 20, para. [82]), and specifically the release rate and the duration of the release (page 4, para. 15, 16; page 8, para. 28 and 29; page 20, para 82; page 13, para 51). Sirhan teaches that the therapeutic agent is

associated at least in part with the structure that is indirectly or directly coupled to the device in configurations (page 6, para. 23) that include the therapeutic agent being part of the polymer coating the device. Specifically, Sirhan teaches therapeutic capable agents such as the ones referred to above to be associated with expandable structures in the form of a stent having surfaces (page 5, para. [0020]; para. [0021], line 13). The therapeutic capable agents are polymeric material that contain therapeutic capable agents that are linked together by suitable linkages that dissociates to release the subunits of the agent in contact with tissue or fluid (page 8, para.[30]; page 29, para. [113]) and the agents are mycophenolic acid/adipic or mycophenolic acid/aspirin and/or adipic (para. [30]), some other specific therapeutic capable agents are rapamycin, methotrexate, camptothecin, TACROLIMUS, prednisolone, GEMCITABINE and combinations (page 21, para. [83]). Another therapeutically capable agent may act in synergy with the therapeutic capable agent or agents (page 11, para. [41]), the another therapeutically capable agent is selected from anti-cancer agents, chemotherapeutic agents, thrombolytics, vasodilators, antimicrobials, biologic agents, acetylsalicylic acid, antimicrobials or antibiotics, antimitotics and others named at page 11, para. [42]. Sirhan contemplates employing second compound that may be the same as the therapeutic capable agent of the device and the second compound are mycophenolic acid, rapamycin and their respective pro-drugs, metabolites, derivatives and combinations (page 17, para. [65]; page 41, para. [161]). In some embodiments, the device comprises multiple layers (see the whole document with emphasis on paragraphs [48], [49], [129]) and the thickness of the coat is at from about 0.01 μm to about 100 μm, with a preferred range of from about 0.1 μm to about 50 μm (page 42, para. [162]).

4. The stent of Sirhan meets medical devices of claims 80, 19-21, 30, 32, 52 and 82; stent meets claims 18, 40, 41, 56-58; the therapeutic capable agents such as the anti-inflammatories, salicylic acid, the antibiotics, methotrexate meeting the requirements for active agents incorporated into the polymer backbone required by claims 80 and 21. When the second compound is rapamycin, claim 82 is met. Coating thickness of from about 0.01 μm to about 100 μm or of from about 0.1 μm to about 50 μm is the species of the recited genus of thickness of 0.1 μm to 10,000 μm (100 nm to 1 cm) or 0.5 μm to 2,000 μm (0.5 μm to 2.0 mm) so that the species anticipating the genus meets claims 19, 20, 56 and 57. Claims 21 and 58 recite the properties of the device and the claims are thus met. Sirhan contemplates the presence of combinations of therapeutic capable agents (page 20, para.[82], another therapeutic capable agent (page 11, para. [42]) and second compound (page 17, para. [65]; page 41, para. [161]) so that the presence of a third active agent is contemplated and thus meets claims 30 and 32 with the release of the active agent under physiological conditions being the properties of the device. Further, the device of Sirhan has at least two surfaces (page 5, para. [20], page 6, para. [21], page 7, para. [24], page 12, para. [46], page 14, para. [54], page 15, para. [59]) so that claims 40 and 41 are met.

Response to Arguments

5. Applicant's arguments filed 1/25/2010 have been fully considered but they are not persuasive.

6. Applicant argues on pages 6 of 13 to 9 of 13 that Sirhan does not anticipate the pending claims because the elements disclosed by Sirhan are not "arranged as in the claims" according to the findings in the VeriSign (see last paragraph of page 6 of 13 of applicant's remarks) decision,

and the findings in the Ecolochem (see first full paragraph of page 7 of 13 of applicant's remarks) even though the Sirhan reference teaches all the elements of the claims; applicant argues that the second compound in Sirhan is administered separately not with the (see page 8 of 13 in the paragraph bridging pages 7 and 8 of 13 which according to applicant; that Sirhan does not prepare any devices comprising polymer having active agent incorporated into the backbone; that Sirhan does not direct the artisan to the claimed invention without picking and choosing and combining various disclosures that are not directly related to each other and that Sirhan does not teach or suggest that rapamycin can be dispersed within the polymer matrix.

7. Response: The examiner has carefully considered applicant's arguments. The examiner maintains that Sirhan anticipates claims 18-21, 30, 32, 40, 41, 56-58, 80 and 82. Sirhan teaches the medical device (current amendment) in the form of a stent that has multiple layers and that have polymeric materials that contain therapeutic capable agents (see paras. [30], [113] of Sirhan). The second component can also be "a therapeutic capable agent," or "another therapeutic capable agent" or bioactive compound (see para. [62]). The "another therapeutic capable agent" is expected to act in synergy with the "therapeutic capable agent" (para. [41]) and Sirhan is clear that the "another compound" or "another therapeutic capable agent" is part of the device (para. [40]), which is the device comprising the polymeric materials that contain therapeutic capable agents. Therefore, when the second compound is the "another therapeutic capable agent" the second compound is part of the device and is also dispersed or part of the polymeric material. Therefore, the disclosed medical device of Sirhan anticipates the claimed medical device of claim 80 and the decision of VeriSign and Ecolochem is not violated. A reference is not limited by its working examples, but the reference must be evaluated as a whole

for what it teaches. In the instant case, the Sirhan reference is considered as a whole and is found to teach the medical device of claim 80. No picking and choosing has been employed in the consideration of the Sirhan reference as a whole and the disclosure of second compound is tied with the disclosure of the "another therapeutic capable agent."

8. The examiner also notes that paragraphs [30] and [113] teach that the "therapeutic capable agent moieties are polymerized and associated to one another through suitable linkages (e. g. ethylenic) forming polymeric therapeutic capable agent. Once the polymeric therapeutic capable agent is brought into contact with tissue or fluid such as blood, the polymeric therapeutic capable agent subunits disassociate. Alternatively, the therapeutic capable agent may be released as the polymeric therapeutic capable agent degrades or hydrolyzes, preferably, through surface degradation or hydrolysis, making the therapeutic capable agent available to the susceptible tissue site, preferably over a period of time," (for paragraph [30]) and "therapeutic capable agent moieties are polymerized and associated to one another through suitable linkages (e. g. ethylenic) forming polymeric therapeutic capable agent. Once the polymeric therapeutic capable agent is brought into contact with tissue or fluid such as blood, the polymeric therapeutic capable agent subunits disassociate. Alternatively, the therapeutic capable agent may be released as the polymeric therapeutic capable agent degrades or hydrolyzes, preferably, through surface degradation or hydrolysis, making the therapeutic capable agent available to the susceptible tissue site, preferably over a period of time," for paragraph [113]. Sirhan specifically discloses therapeutic capable agents forming polymeric product that dissociate in tissues and paragraph [116] also states that the therapeutic capable agent is a polymeric therapeutic capable agent.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 18-21, 30, 32, 40, 41, 52, 56-58 and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (WO 2002/056790) in view of Ragheb et al. (US 6,730,064 B2) for reasons of record.

11. Sirhan has been described above as anticipating claims 18-21, 30, 32, 40, 41, 52, 56-58, 80 and 82. However, while Sirhan teaches the use of anti-neoplastic agents, Sirhan's drug polymer used in the coating does not have paclitaxel as required by claim 81. Specifically, the abstract of Sirhan says that the device is used to reduce restenosis. Ragheb teaches an implantable medical device coated with composition that contains paclitaxel that inhibits restenosis (see claims 1 and 18). Therefore, taking the teachings of Sirhan, one having ordinary skill in the art at the time the invention was made would reasonably expect that including paclitaxel as a specific drug would successfully inhibit restenosis as taught by Ragheb and as contemplated by Sirhan.

Response to Arguments

12. Applicant's arguments filed 1/25/2010 have been fully considered but they are not persuasive.

13. Applicant argues that Sirhan does not render the claims obvious because Sirhan does not teach all the elements of the claims.

14. Response: The examiner disagrees in view of the response provided above and incorporated herein. No picking and choosing is necessary in this case because when Sirhan is considered as a whole, it is clear that Sirhan contemplates medical device having multiple layers and a device that comprises polymeric material that comprises active agents within backbone of the polymer and a second compound that can be "another therapeutic capable agent."

15. Applicant also argues that Sirhan does not mention paclitaxel and that Ragheb does not remedy the deficiencies because Ragheb teaches a "vast range of drugs" for the material in the layer and indicates that paclitaxel can be coated onto stents.

16. Response: The examiner agrees that Ragheb in column 8, lines 7-10 states that "A vast range of drugs, medicaments and materials may be employed as the bioactive material in the layer 18," and also agrees with applicant that Sirhan does not mention paclitaxel. It is the lack of mention of paclitaxel in Sirhan that lead to the rejection of claim 81 under 35 USC 103(a). However, Ragheb is directed to coated implantable devices for delivery of active agents and one of the goals is to prevent restenosis (column 2, lines 50-52; column 5, lines 36-38) and in column 14, lines 36-45, as partially acknowledged by applicant, and again in claims 1 and 18, Ragheb teaches that stents coated with anti-proliferative agents such as paclitaxel inhibit restenosis. Thus, because, Sirhan uses the coated stent to reduce restenosis and Ragheb also uses its coated stent to reduce restenosis, also because one of the active agent class of drugs for reducing the restenosis in Sirhan is an anti-neoplastic agent and paclitaxel used by Ragheb is an antineoplastic agent, which is also very well known antineoplastic agent, that makes the combination of Ragheb and Sirhan proper with Ragheb properly remedying the deficiency of Sirhan.

17. Therefore, the rejection of claims 18-21, 30, 32, 40, 41, 52, 56-58 and 80-82 under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (WO 2002/056790) in view of Ragheb et al. (US 6,730,064 B2) is maintained.

18. No claim is allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618